Standard Operating Procedure –

Data Operations for Integrated Summary of Safety (ISS) & Integrated Summary of Efficacy (ISE) Reporting

This cover sheet controls the layout and components of the entire document.

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Note: This document will be issued for training at the Issue Date. The document will become available for use to trained personnel on the Effective Date. Before using this document, make sure it is the latest revision as posted on the caBIG™ website.

Revision History

Revision	Date	Author	Change Reference	Reason for Change
1.0	February 28, 2006	SOP WG Review	All pages	Document Creation
1.0	February 28, 2006	SOP WG Approval	All pages	Document Creation
1.0	March 14, 2006	BP SIG Approval	All pages	Document Creation
1.0	October 30, 2006	BP SIG/SOP WG	All pages	Initial release.

1. Purpose

This Standard Operating Procedure (SOP) describes the data operations that support the reporting of Integrated Summary of Safety (ISS) and Integrated Summary of Efficacy (ISE) data.

2. Scope

This SOP applies to all clinical research trials covered under the caBIG™ environment and sponsored by the National Cancer Institute (NCI) that must meet regulatory, periodic safety reporting requirements, and:

- Are conducted to support an investigational new drug application (IND) for review to the US Food and Drug Administration (FDA), or
- Are used to support the safety and efficacy findings to support an application for FDA approval to market a new drug (NDA).

3. Requirements

3.1 Data from well-controlled clinical research trials are collected and integrated to support the safety and efficacy study reporting requirements.

3.2 The Statistical Analysis Plan (SAP) will detail the planned statistical analysis associated with the clinical study; the detailed requirements and parameters for the reporting database; and statistical programs/output reports for the reporting of safety and efficacy findings.

4. References/Regulations/Guidelines

Section	SOP Number	Title
4.1	N/A	ICH E3: Guideline, Structure and Content of Clinical Study Reports
4.2	N/A	ICH E6: Guideline, Good Clinical Practice
4.3	N/A	ICH E9: Guideline, Statistical Principles for Clinical Trials
4.4	N/A	Title 21 Part 312.32: Investigational New Drug Application
4.5	N/A	Title 21.314.50(d)(5)(vi) and (3)(v): Applications for FDA Approval to Market a New Drug; Safety and Efficacy Findings Report Requirements
4.6	N/A	FDA Final Guidance Document: Providing Regulatory Submissions in Electronic Format--Human Pharmaceutical Applications and Related Submissions Using the eCTD Specifications. Final Guidance,

Section	SOP Number	Title
		October 2005.
4.7	IT-005	SOP for Standard Programming

5. Roles & Responsibilities

Role	Responsibility
Programmer	• Develop programming for report formats (ISS & ISE shell) required by the regulatory authorities. • Update ISS/ISE shell, when required.
Clinical Study Team	• Provide information on safety and efficacy findings, when required. • Provide updates on safety and efficacy findings for periodic reporting.
Study Statistician	• Draft ISS and ISE shell. • Update shell, when appropriate. • Analyze and report data in approved format, to meet periodic reporting requirements.

6. Attachments

This SOP will be used in conjunction with the following attachments. These attachments must be used to support data operations for clinical research trial adopters conducting trials under the caBIG™ umbrella. The attachments can be customized by individual research sites to accommodate format and content in accordance with local guidelines and/or requirements.

TITLE	DESCRIPTION
1) Procedure Description for Study Reports ISS/ISE Format	This documents the processes for developing the ISS/ISE under the caBIG™ umbrella.
2) Process Flow for Study Reports ISS/ISE Format	This document identifies the workflow activities, by role, for the steps identified in the ISS/ISE Format procedure.